refers to prevention. The verbiage has been changed by omitting any reference to preventing or prevention, on the basis that "prevention" is subsumed under "treatment" as a subset thereof, and is therefore redundant. In this regard it is noted that Webster's Ninth New Collegiate Dictionary, Merriam-Webster Inc., Publishers, Springfield, Massachusetts, USA, Copyright 1986, at page 933 defines "prevent", *inter alia*, as 1archaic **a:** to be in readiness for (as an occasion) **b:** to meet or satisfy in advance **c:** to act ahead of ...**4:** to hold or keep back : HINDER; STOP. Given the common dictionary meaning, one skilled in the art would realize that treatment includes a stoppage which may be temporary, i.e., a prevention, and it is on this basis that the amendment has been made. Applicant's indeed state in their specification:

> An advantage of controlled release, particularly sustained-release formulations according to the present invention is that a patient receiving them would have improved sexual function for a sustained period of time following administration (such as 6-24 hours, for example 12-18 hours), and so be ready for sexual activity at almost any time. This would allow a more spontaneous sex life to be pursued. [Spec at page 5, lines 22-26]

Clearly the above language refers to a "prevention" (for example, as defined in the dictionary) and which those skilled in the art would regard as being within the ambit of "treatment". It is accordingly respectfully requested that the rejection under 35 USC 112 of claims 24-27 and 30 be withdrawn as having been obviated.

Claims 1-21 and 24-30 stand rejected under 35 USC §102(e) as being anticipated by Stella et al, US 6,046,177. The Examiner stated, in pertinent part:

> See Abstract, column 24, line 53. The examples show the various dosage forms of applicants. One skilled in the art would immediately envision incorporating sildenafil into said dosage forms to provide a controlled release sildenafil formulation. The formulation adjuvants are shown in columns 25-28. Osmotic pump tablets are shown in column 16, lines 17-38. The Stella et al dosage forms utilized the same conventional excipients including hydroxy propyl methyl-cellulose and Eudragit coatings. See columns 16-18. [1/18/01 Office Action at pages 3-4].

The rejection is traversed on the basis that Stella is not a reference against the instant application. The filing date of US 6,046,177 is Jan. 13, 1999. All three of Applicants' priority documents (which were submitted when this application was filed in the US and which have been acknowledged as having been received) are dated prior to 1999, and Applicants hereby invoke their right of foreign priority under 35 USC 119 to the extent necessary to antedate '177.

For completeness, Applicants note they are aware that US 6,046,177 is a Continuation-In-Part of US 5,874,418, filed May 5, 1997, copy enclosed herewith. However, the disclosure of the parent is certainly different from, and in general much decreased relative to, '418. For example, the Examiner singled out the '177 disclosure at



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column 24, line 53, presumably for its disclosure of VIAGRA®, registered trademark for sildenafil citrate, currently the only commercially marketed form of any cGMP $PDE_V$ inhibitor. This disclosure does not occur in the parent '418 application, however.

Claims 1-21 and 24-30 stand rejected under 35 USC §103(a) as being unpatentable over Stella et al. US 6,046,177. The Examiner stated, in pertinent part:

> Stella et al shows controlled release dosage forms as explained above. The reference further shows conventional excipients and active agents including sildenafil. A specific dosage form of sildenafil is not shown. Stella et al does show it is well known to incorporate drugs into the controlled release dosage forms for treating sexual dysfunction. The reference shows testosterone incorporated into an osmotic pump dosage form. See column 20, line 58 through column 21, line 4, example 11. It would have been obvious to one of ordinary skill in the art to incorporate sildenafil in place of testosterone in the osmotic pump dosage form of Stella et al. The motivation being a desire to obtain optimum effect in alleviating sexual dysfunction. [1/18/01 Office Action at pages 4-5]

Applicants' discussion from above is incorporated herein by reference. That is, the rejection, insofar as it is based on the '177 patent, is traversed on the basis that '177 is not a reference.

Again, and for completeness, to the extent that the rejection might be based on the common disclosure of the parent '418 patent, the rejection is traversed on the basis that such a rejection would need to be (impermissibly) based on a hindsight and/or an "obvious to try" standard. The '418 patent contains disclosure relating to controlled release formulations of cyclodextrin complexes with numerous compounds. None of that disclosure overlaps with the controlled release formulations containing a cGMP $PDE_V$ inhibitor that Applicants have claimed, however. None of the '418 disclosure suggests $PDE_V$ controlled release formulations, especially sildenafil controlled release formulations, and certainly nothing in '418 provides any expectation that cGMP $PDE_V$ controlled release formulations would be useful or have any of the advantages enumerated by Applicants in their specification. Accordingly, any rejection of Applicants' claimed invention over '418 would have to be from the standpoint that it is obvious to try because '418 does not suggest the invention or provide any expectation of success in achieving it. The law is emphatic that "obvious to try" is NOT the test of obviousness under 35 U.S.C. §103, however. Both the suggestion of an invention and an expectation of success must be based in the prior art. American Hospital supply Corp. v. Travenol Laboratories, Inc., 223 USPQ 577, 582 (Fed. Cir. 1984). The Federal Circuit has explained the proper test:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success**, viewed in light of the prior art. **Both th suggestion and th xpectation of succ ss must b found d in th prior art, not in the applicant's disclosure** (emphasis added).



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In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

Date: July 18, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES

24. (Amended) A method of treating ~~or preventing~~ sexual dysfunction, which comprises administering a controlled-release formulation, as defined in claim 1, but without proviso, to a mammal in need of such treatment ~~or prevention~~.

30. (Amended) Products containing a controlled-release formulation as defined in claim 1, but without proviso, and a cGMP PDE-5 inhibitor in immediate release form, as a combined preparation for simultaneous, separate or sequential use in the treatment ~~or prevention~~ of sexual dysfunction.



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